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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/620,038	07/20/2000	Udo Hoss	RDID 0050 US	3787

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Attn: Jill L. Woodburn
The Law Office of Jill L. Woodburn, L.L.C.
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EXAMINER
CHAUDHRY, MAHREEN F

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/620,038	HOSS ET AL.	
	Examiner	Art Unit	
	Mahreen Chaudhry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-67* is/are pending in the application.

4a) Of the above claim(s) *51-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 23-50, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I and II are not patentably distinct. This is not found persuasive because the groups are related as process and apparatus for its practice which are separate and distinct inventions and therefore properly restrictable.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite with regard to the specific method by which the glucose concentration in a body fluid is determined. The claims recites the measurement of glucose in the dialysate and adjusting the starting glucose concentration in the perfusate but does not recite a specific method step in which the glucose concentration in the body fluid is determined. It is noted that the specification recites that glucose concentration in the body fluid may be determined in two ways, either using the momentary starting glucose concentration in the

perfusate as a measure of body fluid glucose concentration or determination of glucose concentration directly from obtained measurement signals. Since the specific method for the determination of the body fluid glucose concentration is considered an essential method step, consider including a correlation step reciting the method by which body fluid glucose concentration is determined.

Claim 23 is unclear as to whether the method of measuring glucose is directed to a one-time measurement of glucose concentration or to a continuous method of determining the glucose concentration. Since the specification appears to be directed to a continuous method of determining glucose and since the step reciting the adjustment of the starting glucose concentration of the perfusate is directed to the a method for continuously determining the glucose concentration, consider specifically reciting that the method is for continuously determining the glucose concentration in a body fluid.

Claim 23 is unclear with regard to "adjusting the starting concentration...in accordance with a command variable..." It is unclear how the glucose content of the perfusate is adjusted to that of the body fluid since the meaning of "a command variable" is unclear. Consider specifically indicating that the command variable corresponds with the glucose concentration in the body fluid and is derived from the measurement signals of the measuring cell.

Claims 25-26 are unclear with regard to the "adjusting variable." It is unclear how the adjuster obtains an "adjusting variable" and how this variable is then utilized to determine the starting content of glucose in the perfusate.

Claims 25-26 are unclear with regard to "the adjusting step includes determining the starting content of glucose in the perfusate." Since claims 25 and 26 are both ultimately

dependent on claim 23 which recites the adjusting step as "adjusting the starting content of glucose in the perfusate," it is unclear how the starting content of glucose could be both determined and adjusted since the glucose content is adjusted according to a command variable and therefore would not need to be determined from an adjusting variable.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 23-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,091,976 issued to Pfeiffer et al. Pfeiffer et al. disclose a method for the measurement of tissue glucose concentration comprising inserting a microdialysis probe into a tissue, passing a perfusion solution having a predetermined glucose concentration and determination of the glucose content of the solution that has passed through the microdialysis probe in a test cell (Column 3, Lines 49+). Pfeiffer et al. disclose that tissue glucose concentration may be determined from the integrated value of the peak test signals obtained from the test cell (Column 2, Lines 25-31). Pfeiffer et al. further teach that a base line value is determined for the perfusate which corresponds to the initial glucose concentration (Column 2, Lines 18-24). Pfeiffer et al. teaches that tissue glucose concentration may be determined according to the ratio of the peak value to the baseline value multiplied by the initial glucose concentration value and a predetermined calibration value (Column 2, Lines 32-41). Pfeiffer et al. additionally teach that

the perfusion solution is passed through the microdialysis probe in time-separated batches with different flow rates and that the pauses between batches and flow rates are such that the glucose concentration in the perfusion solution equals the tissue glucose concentration (Column 1, Lines 59+; Column 3, Lines 4-10; Column 4, Lines 17-28).

Pfeiffer et al. does not expressly disclose adjusting the initial concentration of glucose in the perfusion fluid to the glucose concentration in the body fluid. However, Pfeiffer et al. does teach a method in which the glucose concentration in the perfusion fluid is equalized to that in the tissue by adjusting the volumetric flow rate as well as diffusion and transport intervals. Pfeiffer et al. teach that the advantage of equalization is to solve the problem of the glucose gradient formed in tissue around the microdialysis probe. Given that Pfeiffer et al. teach the undesirability of the glucose gradient formed in the tissue around the microdialysis probe and that desirability of equalizing the concentration of the perfusion fluid to that of the tissue glucose concentration, it would have been obvious to one having ordinary skill in the art at the time of the invention that appropriately adjusting the glucose concentration of perfusion fluid to that of tissue glucose concentration would also resulting in a decrease in the glucose gradient around the microdialysis probe and thus decrease the time for equilibration.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dempsey et al. disclose an improved microdialysis system for monitoring glucose in which various parameters including flow rate are optimized to increase efficiency.

U.S. Patent 6,013,029 issued to Korf et al. disclose a microdialysis system in which the flow rate is controlled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc
November 13, 2001